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REMARKS

Claims 18-44 and claims 47-52 are pending. Claims 25 and 52 is canceled. Claims 22 and 26 have been amended to recite 65 to 80 weight percent of at least one fat soluble vitamin, which is also recited in previously presented claims 18 and 29. No new matter is presented by way of cancellation or amendment. Upon consideration from the Examiner during the pre-appeal brief conference, the 35 U.S.C. § 112, first paragraph rejection and the 35 U.S.C. § 112, second paragraph rejection have been withdrawn. The amendments to claims 19, 27 and 51 from the pre-appeal brief conference have been entered. In the Office Action mailed January 11, 2007 (hereinafter, the "Office Action"), claims 18-44 and claims 47-52 stand rejected under 35 U.S.C. § 103(a).

The Applicants address the rejections as follows:

A. Rejection of claims 18-44 and 47-52 under 35 U.S.C. § 103(a)

Claims 18-44 and 47-52 are rejected under 35 U.S.C. § 103(a) as being assertedly obvious in light of Schmidt et al. (U.S. Patent No. 4,486,435; hereinafter the '435 patent) in combination with Schmidt (U.S. Patent No. 4,603,143; hereinafter the '143 patent) and Rawlins (U.S. Patent No. 4,719,228; hereinafter "Rawlins"); or Rawlins in view of the '435 patent; or the above-referenced patents disclose alone or in combination. Applicants respectfully disagree.

First, the Office Action has noted that the claims are non-obvious where there is a showing of criticality of the range of 40-50 microns for silica and/or the additional

physical characteristics of the silica sizes shown to be effective. See, the Office Action at page 4, paragraph 1. These data were previously presented in the Declaration of Morris (Sept. 4, 2003, hereinafter the "Declaration of Morris, '03"), attached herewith. Table B of the Declaration of Morris '03 shows that only the 40-50 micron range (not smaller or larger sizes of silica) resulted in a free-flowing powder. Further, the inventor notes that such results are entirely unexpected. *Id.* at point 11. Independent claims 18, 22, 26, and 29, all teach a free-flowing powder using a critical range of 40-50 microns of silica. In addition, claims 22 and 26 have been amended to recite the high fat soluble vitamin loading density which is achieved unexpectedly. Given that such a critical range exists, and that it has been conclusively demonstrated in experiments, Applicants respectfully request withdrawal of the rejection.

Even in light of the data showing criticality, a *prima facie* case of obviousness cannot be established since the cited references do not alone, or in combination, teach, suggest, or motivate one of ordinary skill in the art to arrive at the combination of elements recited in the instant claims. At best, the arguments presented in the Office Action are based on an improper "obvious to try" rationale, which, as stated in the MPEP § 2145 X(B), is "where the prior art [gives] only general guidance as to the particular form of the claimed invention or how to achieve it" [emphasis added].

Specifically, independent claims 18, 22, 26, and 29, disclose, *inter alia*, the common elements of silica particle sizes of 40-50 microns AND addition of starch AND a range of fat soluble vitamin from 65 to 80 weight percent (e.g., as amended in claims 22 and 26). As shown in the Declaration of Morris '03, this combination is critical to achieve the high loading densities (up to 80%) of fat soluble vitamins, which were not be

achieved in any of the cited references. See, the specification of the instant application, paragraph [0020]. In fact, there is no indication in any of the references that higher loading densities can be achieved while maintaining free-flowability, much less any direction as to how arrive at such results.

The burden of meeting a *prima facie* case is not met because the '435 patent and the '143 patent only teach low vitamin-load compositions for silica and vitamin E, i.e., 45-60 percent vitamin as noted in the Office Action. Independent claims 18, 22, 26 and 29 all recite high loading densities (65-80% by weight). The cited references do not teach what silica sizes are necessary to combine with corn starch to create free-flowing powder comprising such a high density of fat soluble vitamins. The Office Action recites Rawlins as disclosing a 40-50 micron range of silica; however, it fails to teach why this range is important to maintaining flowability of high density loading of tocopherols or other fat soluble vitamins. In fact, there is no mention of fat soluble vitamins at all in Rawlins. Consequently, there is no specific teaching or rationale linking corn starch and silica with the combination's ability to increase the loading density of fat soluble vitamins in a free-flowing powder.

Thus, while the Office Action has identified some of the individual elements of the claims, it fails to teach how to combine them to arrive at the recited claims or teach the benefits associated with the claimed compositions. Instead, the Office Action recites the adage that one of skill in the art would be motivated to improve the compositions, and that the recited parameters could be arrived at by experimentation. As stated above, a general motivation (improving something) coupled with the ability to experiment is an improper "obvious to try standard." The courts require more than such

general direction to reach a finding of obviousness. As such, the burden remains on the Examiner to identify specific teachings, and not a general rationale for the obviousness rejection. Even if such a case could be presented, it is rebutted by the data showing the criticality of the claims silica sizes. Thus, Applicants respectfully request withdrawal of the rejection, for at least these reasons.

Applicants note that a reasonable explanation as to why the recited art compositions are stable is lacking. The rationale that the composition "would not be suitable for its intended purpose" as asserted in the Office Action, presupposes that the formulation would be stable. See, page 3 of the Office Action. Stability is a parameter that is affected by the composition, thus, stability but must be demonstrated empirically. No data supports the Examiner's assertion of stability in the cited references, and, thus, Applicants respectfully obviate the rejection.

B. Rejection of claims 18-44 and 47-52 under 35 U.S.C. § 103(a)

Claims 18-44 and 47-52 are rejected under 35 U.S.C. § 103(a) as being assertedly obvious in light of Schmidt et al. (U.S. Patent No. 4,486,435; hereinafter the '435 patent) in combination with Schmidt (U.S. Patent No. 4,603,143; hereinafter the '143 patent) and Rawlins (U.S. Patent No. 4,719,228; hereinafter "Rawlins"); or Rawlins in view of the '435 patent; or the above-referenced patents disclose alone or in combination; further in view of Drake. Applicants respectfully disagree.

As stated above, the claims are non-obvious at least because of the demonstration of a critical range of silica particles at 40-50 microns, and because the

*prima facie* case is not met. The additional Drake reference does not remedy the deficiencies of the previously cited references, either viewed alone or in combination. Drake teaches using corn starch to create a powder comprising an enzyme (e.g., diastase). Those of ordinary skill in the art recognize that large globular proteins, such as enzymes, are water soluble, and, thus, require vastly different formulations than fat soluble vitamins. Therefore, the Drake reference is not relevant to small hydrophobic molecule formulation chemistry, because there is no teaching as to how to use the corn starch to maintain free flowability to fat soluble molecules. Thus, for the foregoing reason, Applicants respectfully request withdrawal of the rejections.

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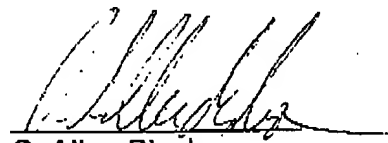
**Conclusion**

For at least the reasons discussed above, Applicants respectfully request reconsideration of the rejections of claims 18-44 and 47-52 and allowance of the claims.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below. Applicants submit that the enclosed fee necessary for consideration of this *Response* is sufficient. Nevertheless, the Commissioner is hereby authorized to charge any additionally required fees deemed necessary for consideration of this *Response* to Account No. 11-1110.

Respectfully submitted,

4/11/07  
Date

  
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